

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/178,484
Applicants : David B. Rozema et al.
Filed : 02/17/2004
Art Unit : 1633
Examiner : Epps Ford, Janet L.
Docket No. : Mirus.030.16.4
For: Intravascular Delivery of Nucleic Acid

Confirmation No. 2135

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Commissioner of Patents
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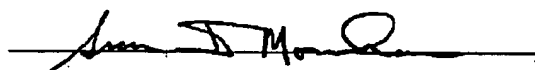
DECLARATION UNDER 37 C.F.R. §1.132

Dear Sir:

I, Dr. Sean D. Monahan, hereby declare as follows:

1. I have a Doctorate in Organic Chemistry from the University of Wisconsin, Madison.
2. I am familiar with the above captioned application and the Heiliger et al. (U.S. Patent 5,453,461) prior art.
3. I am the author of the attached statement regarding the lability of the systems as taught by Heiliger et al.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

 10/24/05
Dr. Sean D. Monahan Date

The invention described in Heiliger, et al. (U.S. Patent 5,453,461) demonstrates the attachment of a polymer component and a biologically active section including biotin, digoxigenin, digoxin, digitoxigenin, digitoxin, and polynucleotides to form biologically active polymers. Heiliger et al. do not discuss or teach the inclusion of the biologically active section using labile attachments, or labile attachments that would result in the cleavage of the biologically active section from the polymer. Heiliger et al. describe systems that have amide, urea, ester, or ether groups within the construct. However, these described systems would not be considered labile under physiological conditions since the conditions required to hydrolyze the described bonds would result in the cleavage of other bonds within the biologically active section thus destroying the biologically active section. The system described by Heiliger would not be thought of as containing labile bonds as is commonly understood in the delivery of biologically active macromolecules.



Sean D. Monahan, Ph.D.

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